

Contact: Maria Cilenti - Director of Legislative Affairs - mcilenti@nycbar.org - (212) 382-6655

REPORT ON LEGISLATION BY THE ANIMAL LAW COMMITTEE

S. 1256

Sen. Feinstein

Preventing Antibiotic Resistance Act of 2013

H.R. 1150 Rep. Slaughter Preservation of Antibiotics for Medical Treatment Act of 2013

AN ACT to amend the Federal Food, Drug, and Cosmetic Act to preserve the effectiveness of medically important antimicrobials used in the treatment of human and animal diseases.

THIS LEGISLATION IS APPROVED

SUMMARY OF THE PROPOSED LEGISLATION

The proposed legislation is intended to combat the proliferation of antibiotic-resistant bacteria, and the resultant serious risk to public health, the environment, and animal welfare, as a consequence of the nontherapeutic uses of certain drugs on food-producing animals. The proposed legislation would amend the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.) to require the Food and Drug Administration ("FDA") to prohibit the use of antibiotics in ways that accelerate the development of antibiotic-resistant bacteria. It calls for producers of animal agricultural products seeking or holding approvals for the use of antibiotics on farm animals to demonstrate they are using antibiotics solely to treat clinically diagnosable diseases, and not to promote animal growth, feed efficiency, weight gain, or for routine disease prevention.¹ The legislation requires that the nontherapeutic use of important antimicrobial drugs² be phased out of use in animal agriculture within two years of the date of its enactment subject to certain exceptions.

² "The term '*medically important antimicrobial*' means a drug that is intended for use in food-producing animals; and is composed wholly or partly of any kind of penicillin, tetracycline, macrolide, lincosamide, streptogramin,

¹ "The term '*therapeutic use*', with respect to a medically important antimicrobial, means the use of antimicrobials for the specific purpose of treating an animal with a documented disease or infection. Such term does not include the continued use of such an antimicrobial in the animal after the disease or infection is resolved." (S. 1256 Sec. 4[b]/H.R. 1150 Sec. 6B). "The term '*nontherapeutic use*' – (i) means administration of antibiotics to an animal through feed or water (or, in poultry hatcheries, through any means) for purposes (such as growth promotion, feed efficiency, weight gain, or disease prevention) other than therapeutic use or non-routine disease control, and (ii) includes any repeated or regular pattern of use of medically important antimicrobials for purposes other than therapeutic use or nonroutine disease control." *Id.* "The term '*nonroutine disease control*' means the use of antibiotics in the feed or water of an animal that is not sick, where in can be shown that a particular disease is, or is likely to be, present on the premises because of a specific, non-customary situation." (S. 1256 Sec. 4[b]/H.R. 1150 Sec. 6E). "The term '*noncustomary situation*' does not include normal or standard practice and conditions on the premises that facilitate the transmission of disease." (S. 1256 Sec. 4[b]/H.R. 1150 Sec. 6D).

Within two years of enactment, the proposed legislation would generally prohibit the administration of medically important antimicrobials to a food-producing animal for nontherapeutic use, subject to some exceptions. First, with respect to the use of such drugs that were approved for administration prior to the effective date of the amendment, the proposed legislation would amend Section 360b of the Federal Food, Drug, and Cosmetic Act (FDCA) to require the Secretary to withdraw approval of medically important antimicrobials for nontherapeutic purposes in foodproducing animals two years following the effective date of the legislation subject to certain exceptions. First, the drug would not be subject to automatic withdrawal two years from the date of enactment if (i) the Secretary makes a written determination that "there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the nontherapeutic use of the drug," either as demonstrated by the applicant itself or by the Secretary sua sponte. Additionally, where a drug in question has been granted an exemption under Section 505 (i) of the Act as a medically important antimicrobial, then the date of withdrawal of approval shall be two years after the date of the exemption. (S. 1256 Sec. 4[b]/H.R. 1150 Sec. 3). Next, with respect to new applications for the use of such drugs, the proposed legislation would amend Section 360b(d)(1) of the FDCA to require the rejection of an application for the use of a medically important antimicrobial for nonroutine disease control in food-producing animals where an applicant has "failed to demonstrate that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable, in whole or in part, to the nontherapeutic use" of such a drug. (S. 1256 Sec. 4[b]/H.R. 1150 Sec. 4).

The administration of medically important antimicrobials to a food-producing animal for nonroutine disease control would still be permitted where the following criteria are met: (1) there is a significant risk that a disease or infection that is present on the premises will be transmitted to the food-producing animal; (2) the administration of the medically important antimicrobial is necessary to prevent or reduce the risk of transmission of that disease or infection; (3) the medically important antimicrobial is administered to the food-producing animals for the shortest duration possible to prevent or reduce the risk of transmission of the disease or infection; and (4) the medically important antimicrobial is administered at a scale no greater than the barn, house or pen level, and to the fewest animals possible to prevent or reduce the risk of transmission of the risk of transmission of the disease control in a food-producing animal medically important antimicrobial for nonroutine disease control in a food-producing animal where the Secretary determines that "there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to such use of the medically important antimicrobial and such use does not threaten the public health."³ Id.

aminoglycoside, sulfonamide, or cephalosporin; or a drug from an anti-microbial class that is listed as 'highly important', 'critically important', or 'important' by the World Health Organization in the latest edition of its publication entitled 'Critically Important Antimicrobials for Human Medicine' (or a successor publication)." (S. 1256 Sec. 4[b]/H.R. 1150 Sec. 6A).

³ Such determination must be made in writing by the Secretary based on "a risk analysis of the drug conducted by the Secretary and other relevant information."

JUSTIFICATION

Although the development of antibiotics has been one of the most important scientific achievements in the treatment of disease in the twentieth century, the proliferation of antibiotic-resistant bacteria due to the overuse of antibiotics now represents one of the greatest public health threats of the twenty-first century. In September 2013, the Center for Disease Control ("CDC") issued a report urging immediate action to prevent potentially catastrophic consequences from the growing public health threat from antibiotic-resistant bacterial infections, which reportedly afflicts more than two million people annually, with at least 23,000 dying as a result.⁴ While Congress has taken steps to curb antibiotic overuse in human medicine, it has not yet addressed the overuse of antibiotics in agriculture which has been recognized by the CDC and other public health authorities as a primary cause of the proliferation of antibiotic resistant bacteria.⁵

Antibiotics are used for three main purposes in livestock production: (1) as therapeutics for managing clinically apparent diseases, (2) prophylactics for disease prevention, and (3) to promote growth.⁶ The widespread use of intensive confinement methods of food-producing animals such as gestation crates for pigs,⁷ veal crates for calves⁸ and battery cages for hens,⁹ which so severely

⁵ *Id.* at 36-37; Id. at 37 ("[b]ecause of the link between antibiotic use in food-producing animals and the occurrence of antibiotic-resistant infections in humans, antibiotics should be used in food-producing animals only under veterinary oversight and only to manage and treat infectious diseases, and not to promote growth."); *Id.* at 11 (concluding that "the use of antibiotics for promoting growth is not necessary and the practice should be phased out").

⁶ U.S. Dept. of Agriculture, Animal and Plant Health Inspection Service et al., Antimicrobial Resistance Issues in Animal Agriculture 16 (May 2007), *available at*

http://www.aphis.usda.gov/animal_health/emergingissues/downloads/antiresist2007update.pdf (last visited Jan. 2, 2014).

⁴ U.S. Department of Health and Human Services, Center for Disease Control and Prevention, "Antibiotic Resistance Threats in the United States, 2013," p.6, April 23, 2013, *available at* <u>http://www.cdc.gov/drugresistance/threat-report-</u>2013/pdf/ar-threats-2013-508.pdf (last visited Nov. 26, 2013). A recent study performed by scientists from Johns Hopkins, the University of North Carolina, and George Washington University, found that the heavy use of antibiotics in livestock raised for human consumption may be behind the increase in superbugs, including Methicillin-Resistant Staphylococcus aureus (MRSA). *See* Rinsky JL, Nadimpalli M, Wing S, Hall D, Baron D, et al. (2013), *Livestock-Associated Methicillin and Multidrug Resistant Staphylococcus aureus Is Present among Industrial, Not Antibiotic-Free Livestock Operation Workers in North Carolina*, PLoS ONE 8(7), July 2, 2013, *available at* http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0067641 (last visited Nov. 26, 2013).

⁷ Gestation crates for breeding sows are individual, concrete-floored metal stalls measuring 2 – 2.3 feet wide by 6.6 – 6.9 feet long, which is only slightly larger than the animal and so severely restrictive of her movement that a sow is unable to turn around within the crate. *See* Commission of the European Communities, 2001. COM (2001) 20 final 2001/0021 (CNS) Communication from the Commission to the Council and the European Parliament on the welfare of intensively kept pigs in particularly taking into account the welfare of sows reared in varying degrees of confinement and in groups. *See also* Proposal for a Council Directive 91/630/EEC laying down minimum standards for the protection of pigs, *as cited in, An HSUS Report: Welfare Issues with Gestation Crates for Pregnant Sows*, Humane Society of the United States, Fen 2013, <u>http://www.humanesociety.org/assets/pdfs/farm/HSUS-Report-on-Gestation-Crates-for-Pregnant-Sows.pdf</u> (last visited Jan. 2, 2014).

⁸ Veal calves may be tethered or confined for as long as sixteen weeks in two-foot-wide crates that do not permit them to walk or extend their limbs, leading to such physical ailments as digestive problems, discomfort, impaired locomotion, and a greater susceptibility to disease. *See* "An HSUS Report: The Welfare of Animals in the Veal

restrict movement and natural behaviors that the animals in these facilities may not be able to turn around or walk, is recognized as a primary impetus for the administration of non-therapeutic antibiotics to food-producing animals both to manage existing disease induced by such conditions and to prevent disease commonly associated with such conditions.¹⁰ Additionally, the practice of using antibiotics to promote growth of farm animals is also commonly associated with intensive confinement farming facilities and has increased in use exponentially since it was first introduced in the 1940s.¹¹ This is partly because antibiotics' effectiveness as a growth promoter has declined and more antibiotics are needed.¹² As a result of these practices, today over 80% of American pig farms, cattle feedlots, and sheep farms administer drugs in feed or water¹³ and roughly 100% of chickens and turkeys receive antibiotics in their food.¹⁴ It is estimated that at least 80% of all antibiotics disseminated in the United States are administered to food-producing animals for nontherapeutic purposes, including growth promotion, and to compensate for crowded, unsanitary, and stressful farming and transportation conditions, as opposed to being used for human health.¹⁵

Industry," Humane Society of the United States, July 2012, available at

http://www.humanesociety.org/assets/pdfs/farm/hsus-the-welfare-of-animals-in-the-veal-industry.pdf (last visited Nov. 26, 2013); Farm Sanctuary, The Welfare of Cattle in Dairy Production: A Summary of the Scientific Evidence, April 2011.

⁹ Approximately 98% of egg-laying hens in the United States are confined in battery cages, where they also cannot turn around, or spread their wings. Each bird is allotted an average space of about 61 square inches, smaller than an 8 ½ by 11 inch piece of paper. *See* United Egg Producers, United Egg Producers Animal Husbandry Guidelines for U.S. Egg Laying Flocks, *available at* <u>http://www.unitedegg.org/information/pdf/UEP_2010_Animal_Welfare_Guidelines.pdf</u> (last visited Nov. 26, 2013).

¹⁰ Pew Commission on Industrial Farm Animal Production (2008). *Putting Meat on the Table: Industrial Farm Animal Production in America.* Johns Hopkins Bloomberg School of Public Health, *available at* <u>http://www.ncifap.org/_images/PCIFAPFin.pdf</u>. (last visited Nov. 26, 2013) (noting that "Industrial farm animal production systems are also highly dependent on intensive animal confinement, which commonly requires the use of antimicrobials to prevent disease, not just to treat it.").

¹¹ Robyn L. Goforth & Carol R. Goforth, Appropriate Regulation of Antibiotics in Livestock Feed, 28 B.C. ENVTL. AFF. L. REV.39, 46 (2000).

¹² *Id.* at 46-47.

¹³ S. 619, 111th Congress 4:4-14 (2009) & H.R. 1549, 111th Congress 4:10-20 (2009)

¹⁴ BOARD ON AGRICULTURE, THE USE OF DRUGS IN FOOD ANIMALS: BENEFITS AND RISKS 181 (1999), *available at* <u>http://books.nap.edu/openbook.php?record_id=5137&page=181</u> (last visited Nov. 26, 2013).

¹⁵ Helena Bottemiller, *Most U.S. Antibiotics Go to Animal Agriculture*, Food Safety News, Feb. 24, 2011, *available at* <u>http://www.foodsafetynews.com/2011/02/fda-confirms-80-percent-of-antibiotics-used-in-animal-ag/#.UmFiPZTSM9I</u> (last visited Nov. 26, 2013) (quoting Congresswoman Louise Slaughter (D-NY) as stating "We already knew that 13.1 million kilograms of antibacterial drugs were sold for use on animals in 2009. Recently, I was able to confirm with the FDA that only 3.3 million kilograms were are sold each year for human use in 2009. Using these figures, I have determined that 80 percent of all antibacterial drugs are dedicated to use on animals."). *See also* 2011 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, U.S. Food and Drug Administration, 2011, *available at* <u>http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf</u> (last visited Nov. 26, 2013) (indicating that in 2011 29.9 million pounds of antibiotics were administered to food-producing animals in the United States).

The overuse of antibiotics in animal agriculture has been widely recognized as a primary cause of the proliferation of antibiotic-resistant bacteria. For example, the CDC and the FDA have identified the widespread use of antibiotics in food-producing animals as a significant factor in the emergence and transmission of antibiotic-resistant bacteria to humans.¹⁶ Accordingly public health authorities such as the Pew Commission on Industrial Farm Animal Production and the Johns Hopkins Center for a Livable Future have called for a ban on the nontherapeutic use of antibiotics in food-producing animals to reduce the risk of antimicrobial resistance to medically important antibiotics and other antimicrobials.¹⁷

Despite these recommendations there is currently no federal oversight to ensure the judicious use of antibiotics in animal agriculture.¹⁸ The proposed legislation would provide the necessary regulation by generally phasing out the nontherapeutic use of antibiotics in animal agriculture and providing appropriate safeguards to ensure that continued usage of such drugs is based on a reasoned health risk analysis. This legislation is necessary to address the widespread overuse and misuse of antibiotics in animal agriculture in order to preserve the efficacy of vital antibiotics in treating serious diseases in humans, including pneumonia, scarlet fever, rheumatic fever, sexually transmitted infections, skin infections, and pandemics like malaria and plague, as well as exposure to bioterrorism agents such as anthrax.

CONCLUSION

For the aforementioned reasons, the Committee supports the proposed legislation.¹⁹

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¹⁶ See 2013 CDC report, *supra* ("[b]ecause of the link between antibiotic use in food-producing animals and the occurrence of antibiotic-resistant infections in humans, antibiotics should be used in food-producing animals only under veterinary oversight and only to manage and treat infectious diseases, and not to promote growth."); U.S. Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Guidance for Industry, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals", April 13, 2012.

¹⁷ Pew Commission on Industrial Farm Animal Production (2008), *supra; Industrial Food Animal Production in America: Examining the Impact of the Pew Commission's Priority Recommendations*, Johns Hopkins Center for a Livable Future, Fall 2013, *available at <u>http://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-a-livable-future/_pdf/research/clf_reports/CLF-PEW-for%20Web.pdf</u> (last visited Nov. 26, 2013).*

¹⁸ We note that in December 2013 the FDA announced a "voluntary plan with industry to phase out the use of certain antibiotics for enhanced food production." *See* Phasing Out Certain Antibiotic Use in Farm Animals, U.S. Food and Drug Administration, Dec. 11, 2013, *available at*

<u>http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm378100.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery</u> (last visited Dec. 12, 2013). As a voluntary program however, this initiative would not mandate compliance with any proposed phase out in the same manner as the proposed legislation. Accordingly, this Committee believes that adoption of the proposed legislation, which would set mandatory prohibitions on the use of certain antibiotics in food-producing animals, is necessary to adequately protect public health.

¹⁹ We note that more than 375 public, consumer and environmental health groups, including the American Medical Association, the American Public Health Association, and the Infectious Diseases Society of America, also support the proposed legislation. "Feinstein Bill Safeguards Use of Antibiotics in Agriculture", June 27, 2013, *available at* <u>http://www.feinstein.senate.gov/public/index.cfm/2013/6/feinstein-bill-safeguards-use-of-antibiotics-in-agriculture</u> (last visited Nov. 26, 2013).